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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/973,363	02/04/98	GRIFFITHS	R 263PPNTIR117

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EXAMINER
SCHNIZER, R

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 02/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/973,363

Applicant(s)

Griffiths

Examiner

Richard Schnizer

Group Art Unit

1632☐ Responsive to communication(s) filed on _____☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 34-49 _____ is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 34 and 35 _____ is/are allowed.
- ☒ Claim(s) 36-49 _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

An election and preliminary amendment were received and entered as Paper No. 14 on 11/29/99. Claims 1-33 have been canceled in response to the amendment, and new claims 34-54 have been entered. Applicant's election with traverse of group 1 comprising claims 33-47 is acknowledged. The traversal is on the ground(s) that the new claims are linked by a common inventive concept, particularly because the non-elected claims are now dependent on the elected claims. The examiner finds that claims 48 and 49 should be combined with group I as a first method of using the polynucleotides of group I. Claims 50-54 are drawn to proteins and antibodies, and are found to lack a common special technical feature for the reasons of record in Paper No. 12. It is noted that dependency does not cause claims to be linked by a common inventive concept. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

With regard to claims 36-49, directed to polynucleotide sequences that hybridize to the disclosed sequences, Applicants have not sufficiently defined the conditions under which the

hybridizations are to take place. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. In particular, the conditions under which hybridization filters are washed are critical to the sensitivity of the technique. Applicant discloses preferred conditions for moderate and high stringency hybridization incubations on page 9 of the specification, but does not disclose washing conditions. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the hybridization and washing steps. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of the conditions which were actually used by Applicants in the claimed invention, the skilled artisan would not be able to practice the invention and would not be reasonably apprised of its metes and bounds. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-41 are indefinite because they recite hybridization, but lack any description of hybridization conditions. The claims are drawn to nucleotide fragments which specifically hybridize to non-ratite bird W chromosomes but not to other genomic DNA. One of skill in the art appreciates that the specificity of any hybridization signal is critically dependent on hybridization and washing conditions. These conditions are not recited by the claim. Thus practitioners using various hybridization conditions would not know if sequences discovered by hybridization were encompassed by the instant claims or not.

Claims 42-49 are indefinite because they recite required hybridization conditions as “moderate to stringent”, but these conditions are not defined in the claim. Disclosure of these conditions in the claim is required. However, even though the specification defines moderate and stringent hybridization incubation conditions on page 9, it fails to disclose conditions for washing the hybridization filters. Washing conditions have enormous influence on the sensitivity of the hybridization technique. Without disclosure of the washing conditions, a skilled artisan cannot be apprised of the metes and bounds of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 37, and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Delmas et al (Proc. Nat Acad. Sci USA 90(6): 2414-2418, 1993).

Delmas teaches a single polynucleotide with 66.7% homology to SEQ ID No. 2, 44.1% homology to SEQ ID No.3, 45.6% homology to SEQ ID No.4, 45.1% homology to SEQ ID No.5, 51.4% homology to SEQ ID No.10, and 67.2% homology to SEQ ID No.15. In the absence of evidence to the contrary, this polynucleotide is deemed to be able to specifically hybridize under moderate to high stringency conditions to sequences comprised by SEQ ID Nos. 2-5, 10, and 15. See Fig 1, page 2415, and enclosed sequence alignments. Because the sequence of Delmas comprises segments of 100% identity with those of SEQ ID Nos. 2-5, 10, and 15, it is deemed to comprise fragments of nucleotides sequences according to claims 34 and 35, thus claims 36 and 37 are included in this rejection. The specification does not explicitly define a "fragment" as not encompassed by another polynucleotide. Thus Delmas anticipates the claims.

Conclusion

Claims 34 and 35 are allowable.

Claims 36-49 are rejected.

Claims 34, 35, 38-41, 48 and 49 appear to be free of the art.


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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday-Friday from 7:30 to 4:00 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached at 703-308-2035. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.


BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800